

# SureTek Medical 510(k) Summary

**Submitter** SureTek Medical 25-B Maple Creek Circle Greenville, SC 29607  
**Contact** Mike Sammon, Ph.D. 864-299-9743  
**Date** 9/25/05  
**Product** SureTek Reprocessed Electrosurgical Electrodes  
**Classification** Code: NUJ Regulation: 21 CFR 878.4400 Name: Electrosurgical, cutting & coagulation accessories, laparoscopic & endoscopic, reprocessed.

Predicate Devices	Manufacturer/Reprocessor	Device/System Tradenames	510(k)
	Arthrocare	ArthroWand*, PlasmaWand*	K033257, K033584
	Mitek	VAPR*	K963783
	Smith & Nephew	Vulcan*, Saphyre*	K050898
	Linvatec	UltrAblator, Lightwave*	K030720, K050923
	Arthrex	OPES*	K023986
	ValleyLab	Electrosurgical Device	K861112, K051627
	Vanguard Medical Concepts	Reprocessed Arthroscopic Wands	K043198
	Alliance Medical	Reprocessed Soft Tissue Ablators	K012631

**Device Description and Technological Features** Devices are monopolar and bipolar electrosurgical electrodes designed for ablation, resection and coagulation of soft tissue. Instruments consist of one or more distal electrodes, an insulated shaft, and a proximal handle with electrical connections to a compatible electrosurgical unit. Monopolar instruments require concurrent use of a compatible return electrode. Models have varying electrode configurations and tip angles. Some models are equipped with suction tubing for continuous cooling of the ablation site and aspiration of fluids/debris during use. Reprocessed electrodes have equivalent technological characteristics as the predicate devices, i.e. device design, dimensions, energy delivery and system compatibility are unchanged during reprocessing. Device materials are identical with the exception of shaft insulation, which may be replaced with a comparable heat shrink material.

**Intended Use** SureTek Reprocessed Electrosurgical Electrodes are intended for use during general, arthroscopic and endoscopic surgery for RF ablation, resection or coagulation of soft tissue and hemostasis of blood vessels.

**Testing and Standards**

- Simulated-use testing of instruments following maximum number of use and reprocessing cycles found their performance to be substantially equivalent to new, unused devices.
- Product insulation conforms to the relevant safety requirements of ANSI/AAMI HF18 *Electrosurgical Devices*.
- SureTek cleaning process is validated to be effective for decontamination of grossly contaminated instruments under worst case operational conditions.
- Product packaging conforms to all relevant requirements of ISO 11607 *Packaging for terminally sterilized medical devices*, with performance qualifications tested according to EN868-1 and ASTM F88-00, F2906-04, D4169-04a and F1980-02.
- Product sterility and process validation conform to the relevant requirements of ISO 11135 *Medical Devices – Validation and routine control of ethylene oxide sterilization*.
- Products conform to the relevant requirements of ISO 10993 *Biological Evaluation of Medical Devices* for ethylene oxide residuals and biocompatibility of device materials

**Substantial Equivalence** Product testing and comparisons of specifications demonstrate that SureTek Reprocessed Electrodes are substantially equivalent to their predicate devices with respect to device design, technological characteristics, intended use and performance, as well as product packaging, labeling, sterility and safety.

\* Product tradenames are registered trademarks of their respective manufacturers.